Economic Impacts and Implications of Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants
July 25, 2019

Economic Impacts of Draft Guidance:

The Biostimulant Industry has serious concerns regarding the economic implications of the Guidance as currently written. Some of the Industry's partners have already encountered problems with state regulatory agencies due to the Guidance. Outlined in detail below are some of the potential ramifications on the Industry (and state regulatory bodies) if the Guidance is finalized in its current form.

The PBS market in the US is growing every year. It is projected that the global agricultural biologicals market will exceed $4 billion by 2024. Biostimulants are projected to comprise half of the total market, with almost 60% of product lines containing SWE or humic and fulvic acid.[1] In the United States, PBS are not regulated as pesticides. Therefore, any change to the regulation has the potential to place an economic burden on manufacturers, companies producing end-use projects, federal and state regulatory agencies, and growers. Based on Table 4 of the Guidance, PBS having MOA and associated product label claims identified in the Guidance as PR would trigger regulation under FIFRA as a pesticide. The entities directly affected by the Guidance would include manufacturers of PBS and end-use products, third party distributors, and growers, as well as federal and state regulatory agencies. The subsequent comments focus on the affected entities manufacturing, utilizing, and regulating active ingredients most commonly found in PBS products (potassium silicates, SWE, and complex polymeric polyhydroxy acids, including humic acid, fulvic acid, tannins, and organic acids from Leonardite) and provides an economic analysis on the potential impact of the Guidance.

Overview of biostimulants *registered as* fertilizers, soil amendments, *and* plant amendments

Unlike pesticides, fertilizers are not regulated at the federal level, therefore each state has a different regulatory process related to fertilizers. The licensing, registration, and tonnage fees differ by state, as well as the length of term for the registration and/or license. The majority of states renew fertilizer licensing annually; however, California, New Mexico, New York, North and South Dakota, and Washington all have two-year terms. In addition to differing fertilizer regulations and fees, each state has their own pesticide regulation and registration process (fees, length of terms, required years to discontinue, etc.) that they administer based on products registered under FIFRA. Due to these differences, registering products is costly, both in fees and time.

Focusing on a simple keyword search relevant to active ingredients of interest (seaweed, potassium silicate, humic, fulvic, tannin, and leonardite) in state level fertilizer product registries, there are over 500 different products containing at least one of the keywords in their product

[1] Markets and Markets. 2019. Available at: https://www.marketsandmarkets.com/PressReleases/biostimulant.asp

name registered in at least one of the 14 states with public fertilizer product registries.[2] California, Oregon, and Wisconsin have the largest number of registered products containing these ingredients.

As the largest agricultural market in the US, California is of significant importance to manufacturers. Since there is no central database of PBS products, it is likely that there are substantially more products being marketed to and used by growers in both states that register fertilizers and those that do not register fertilizers.

The costs associated with the Guidance are divided into five categories: data development costs, federal registration costs, state registration costs, organic production costs and production costs to manufacturers.

Data Development Required for Federal and State Registration

In order to register products as pesticides under FIFRA, Federal Food, Drug, and Cosmetic Act (FFDCA), and at the state level, manufacturers are required to provide data to support an application for registration or amendment. States, such as California, may require data above what is required by FIFRA. In many cases, data development would take at least two years to complete. Requiring PBS products containing the substances listed in Table 4 to be registered as pesticides would delay registration, disrupting the revenue stream of manufacturers.

As outlined in 40 CFR Part 158, the cost to manufacturers for data development depends on the type of product being registered. Based on product data requirements identified under 40 CFR Part 158(U) for biochemical pesticides and EPA cost estimates, assumptions are considered for a new product where the active ingredient is already registered and for a new active ingredient. The cost for data development for a new active ingredient could cost upwards of $500,000 for one active ingredient; however, for a product where the active ingredient is already registered, the cost could be close to $21,000 per product. For this analysis, it is assumed that data development costs would be incurred equally in the first two years. We also assume that data development would be conducted and submitted concurrently for all products; however, it is more likely that it would take multiple years to complete the trials and submit data for registration.

Annualized costs were calculated over a 5-year time horizon based on a 5% discount rate[3]. A 5-year time horizon was selected based on the longest period for state pesticide registration renewal (Connecticut). It was assumed that the majority of costs would occur in the years immediate following the potential implementation of the Guidance. Both the time horizon and discount rate influence the annualized costs and can be adjusted to estimate a range of costs based on the given time horizon and discount rate. Estimated data development costs for various scenarios and number of products registered are provided in Table 1.

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[2] States with publicly available fertilizer registries include Arizona, California, Delaware, Kansas, Michigan, Minnesota, North Dakota, Oklahoma, Oregon, South Carolina, South Dakota, Vermont, Washington, and Wisconsin.

[3] US EPA, National Center for Environmental Economics, Office of Policy. Guidelines for Preparing Economic Analysis. December 17, 2010 (Updated May 2014). Available at: https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses.

Table 1. Annualized costs of data development for federal registration under FIFRA.

Estimated Data Development Costs	Number of Products Potentially Registered			
	100	250	500	750
	Annualized Costs for Data Development over 5 years (thousand $US)			
$21,700 per product (Low)	$361	$903	$1,806	$2,708
$250,000 per product (Middle)	$4,361	$10,903	$21,806	$32,709
$500,000 per product (High)	$8,722	$21,806	$43,611	$65,417

Assuming between 100 and 750 products would require data development for federal registration and the costs would be incurred in the first two years, the potential annualized costs to manufacturers would range from approximately $361 thousand to approximately $65 million annually, depending on the type of data development required. In addition to data development, the cost would include lost revenue during the data development stage when products could no longer be sold in states as fertilizers. If EPA allowed these products to register under the 25(b) statue, the data development costs would be close to $0; however, the majority of states require registration for 25(b) products and some states would require data development as part of that registration.

At the state level, some states, such as California, have data requirements that exceed federal data development requirements. Manufacturers with products registered as fertilizers in California anticipate that it would take two to three years to secure pesticide registration in California. If manufacturers were not permitted to sell their product during this time period, they would incur substantial market losses depending on the size of the company. For manufacturers with a large market share in California, losses could be as high as $35 million while they wait for their products to move through the registration process or if they choose not to register products in California. According to the fertilizer registry for California, there are at least 100 companies with products registered as fertilizers in California that include potassium silicates, SWE, and/or complex polymeric polyhydroxy acids. If each of these companies lost $10 million, on average, due to lost revenue during the registration process (assuming a 2 year process), the annualized financial burden (5 years using a 5% discount rate) would be approximately $349 million annually. The potential for lost revenue may keep manufacturers with limited capital from moving forward with registration or from entering the market in certain states.

Federal Registration under FIFRA

In order to estimate the potential cost to registrants from registering products containing SWE, potassium silicate, and/or complex polymeric polyhydroxy acids, several assumptions need to be clearly defined. Based on PRIA Fee Categories for Biopesticides, the following actions were considered: 1) New active ingredient with a food use and a petition to establish a tolerance exemption; 2) New active ingredient with a non-food use; 3) New active ingredient with no change to a permanent tolerance exemption; 4) New manufacturing use product (MUP) with a registered source of active ingredient(s); and 5) New MUP/end-use product (EP) with an unregistered source of active ingredient(s). For

ease of estimation and to provide a range, it assumed that all products submitted to EPA for registration would be placed into the same category and in the first year of a 5-year time horizon. The maintenance fees would be paid annually over the remaining 4-years (year 2 to year 5). While the assumptions listed above may not be reflective of what will actually happen if the Guidance is implemented as written, it provides a general range of the potential impact. This estimate does not consider the PRIA timeline, or the time it would take the registrants to develop their registration packages.

As with other pesticides, the estimated cost to registrants registering biopesticide products under FIFRA is directly dependent on the product use and whether the active ingredient has already been registered. Due to the uncertainty surrounding the number of products that may be submitted for federal registration, annualized costs for 100, 250, 500, and 750 products are presented in Table 2. The annualized cost over five years to manufacturers related to federal registration would range from $307 thousand (100 products) to $5.89 million (750 projects). This does not include the cost for data development required as part of FIFRA registration. While annualized costs for 100 and 250 projects are provided, it is unlikely the number of registrations would be below 500 due to the number of PBS registered in states and by Organic Materials Review Institute (OMRI), as will be discussed below. While not included in Table 2, federal regulatory agencies would incur additional costs related to the increase in products submitted for registration, above the pesticides currently in the queue for registration and registration review.

Table 2. Annualized costs (5 years, 5% discount rate) of estimated costs to register products containing seaweed extracts, potassium silicate, and/or complex polymeric polyhydroxy acids under FIFRA.

PRIA Category	Number of Registered Products			
	100	250	500	750
	Annualized costs over 5 years (thousand US$)			
New active ingredient with a food use and a petition to establish a tolerance exemption	$786	$1,964	$3,928	$5,893
New active ingredient with a non-food use	$558	$1,394	$2,788	$4,182
New active ingredient with no change to a permanent tolerance exemption	$529	$1,323	$2,645	$3,968
New manufacturing use product (MUP) with a registered source of active ingredient(s)	$378	$946	$1,892	$2,838
New product MUP/end-use product (EP) with an unregistered source of active ingredient(s)	$307	$767	$1,534	$2,300

State Registration

Once federally registered, pesticides must also be registered at the state level. Currently the majority of products containing SWE, potassium silicate, and/or complex polymeric

polyhydroxy acids are registered as fertilizers at the state level in states where registration is required for fertilizer. The product registration fee for fertilizers ranges from zero to US $200 per product depending on the state, type of products, size of packaging, and other requirements. Some states, such as California, require both a product registration fee and a licensing fee, which can range from $10 to $200 depending on state. Two states have requirements that registrants must continue to register the product for additional years after discontinuing the product.

All 50 states have licensing fees and/or registration fees for pesticides, and, in all cases, they are greater than the cost to register fertilizers, ranging from $90 per product in Wyoming to $1,150 per product in California. Thirty-three states require registrants to continue registering their products for at least one year after discontinuing the product label. In some states, there is the option to register a product as both a fertilizer and a pesticide but that option is limited to only six states.

Using data gathered from state fertilizer registries for products containing SWE, potassium silicate, and/or complex polymeric polyhydroxy acids and total crop sales by state for the 2017 USDA Census of Agriculture, states were divided into two groups: states with field crop sales exceeding non-field crop sales (vegetable, horticulture, and fruit and tree nut) and states with non-field crop sales exceed field crop sales. California and Oregon have the highest number of PBS registered as fertilizers and both are states with high non-field crop sales. For this analysis, states were divided into two categories: high field crop sales and high non-field crop sales. For states with high field crop sales, it was assumed that 150 products per state would be registered as pesticides. For states with high non-field crop sales, it was assumed that 300 products per state would be registered as pesticides. This is a general estimation of the potential number since it is difficult to accurately forecast the number of products that will be registered as pesticides if the Guidance is adopted as written.

The annualized costs were calculated based on similar assumptions as outlined above for the cost of federal registration. The renewal length by state for fertilizer and pesticide registrations was also considered in the analysis. Since PBS products are already registered as fertilizers in some states, an estimated baseline was calculated using data gathered from state fertilizer registries for the minimum registration fee plus licensing fee and the maximum registration fee plus licensing fee for states with fertilizer registration requirements. For states with fertilizer registration but without a public registry, it was assumed that 20 products were registered in each of these states. The baseline represents the potential revenue currently collected at the state level that would either move to a different state department/division for registration or would no longer be collected if products were not registered as pesticides. This revenue estimate does not include the tonnage fee levied by some states nor the additional workload to register more products as pesticides. The estimated differences between the annualized costs for baseline fertilizer registration and pesticide registration are presented in Table 3.

Table 3. Annualized costs (5 years, 5% discount rate) of converting products from a fertilizer registration to a pesticide registration under state pesticide regulation.

Scenario	Estimates Range of Annualized cost over 5 years (thousand $US)
Baseline (Products registered as fertilizers)[a]	$89 - $115
Products registered as pesticides[b]	$2,147
Increase in cost to register products as pesticides	$2,058 - $2,032

[a] Most states include a range of fees based on packaging and type of product.

[b] This does not include the cost of data development required by some states, such as California.

The annualized costs for state registration are greater for pesticide registration as compared to fertilizer; however, as California is the most important market for most PBS manufacturers, the larger concern is how the Guidance will impact registration in California. Manufactures are required to conduct additional trials above what is required federally to register products in California. The additional testing is time consuming and costly, without the guarantee of registration. Even without final guidance, some states are currently referencing the Guidance when answering inquiries regarding PBS registration. It is likely that a subset of manufacturers will choose to not register products in certain states, or leave the market all together. State licensing agencies would experience reduced revenues or a redistribution of workload and revenue.

While this analysis provides the annualized cost over 5 years, the heaviest burden to the manufacturers is the first years when products are being registered. It is unclear if manufacturers will be able to continue to sell their products if they have not completed the registration process as pesticides. Additionally, state registration depends on successful EPA registration.

Organic Production

Many PBS products are certified organic fertilizer products through OMRI. If these products are registered as pesticides with EPA, manufacturers will have to apply for review through OMRI to certify their product as an organic pesticide. There are currently 397 products registered with OMRI as fertilizers with the following keywords in their product name: seaweed, algae, humic, fulvic, potassium silicate, and leonardite. There are only 12 products with these keywords in their product name currently registered with OMRI as pesticides. The cost to change from fertilizer to pesticide registration through OMRI is primarily the initial review fee ($245 per product for a single ingredient product and $810 per product for a multi-ingredient product) and the annual product fee ($155 per year for a single ingredient product and $510 per product annually for a multi-ingredient product). Additionally, while there are products registered as pesticides through OMRI containing the keywords identified above, it is not a guarantee that they will be reviewed by OMRI for consideration as organic pesticides. A further consideration is the complex and time-consuming paperwork, as well as the potential to lose market share if growers choose not to apply products registered as organic pesticides due to marketing concerns by the growers.

Potential economic impact on manufacturers for rebranding, relabeling, supply chain and logistics changes

Under the Guidance, manufacturers may be faced with rebranding and relabeling costs, as well as costs incurred due to changes in supply chains and logistics. These costs vary by size of manufacturer, number of impacted products, and states where manufacturers sell products.

Rebranding

For manufacturers faced with rebranding products to meet the Guidance, the cost depends on the number of products marketed by a manufacturer as well as popularity and complexity of the brand. Rebranding may include reworking and printing marketing materials, social media messaging, training sales team and customers, and adjusting packaging. It is possible that a manufacture may also have to adjust their trademark registration. Manufactures estimate that it would take more than one year to reestablish a new brand, and could cost between $5,000 and $80,000 per product depending on the complexity and scope of the product. If the product is primarily used in an end product formulated by a third party, the branding may be less of an expense as compared to a company that formulates the end-use product and advertises directly to growers.

Relabeling

The costs of relabeling includes more than just new language and graphics associated with a new label. Relabeling may also consist of changes to warehouse management, new packaging, and the cost of registering a pesticide both at the federal and state level, including additional efficacy trials, toxicity evaluations, associated time and fees, and other tasks depending on the product. These costs have been captured in earlier comments; however manufacturers estimate that relabeling costs could as high as $900,000 depending on registration requirements. Excluding data development costs, costs of relabeling are estimated to range between $5,000 and $25,000 per product.

Supply Chain and Logistics Considerations

As with other costs to manufacturers, changes in the supply chain and logistics have a greater impact on manufacturers with fewer products. The cost of supply chain and logistics disruptions could range from $6,000 per product to over $95,000 per product. Supply chain and logistic considerations may include changes to processing of orders, purchases, production plans and schedules, inventory management, transport (inbound, distribution and delivery), warehouse management, and information systems. Costs due to supply chain and logistics changes are dependent on location and specific condition needs for manufacturers and each down-stream customer. There are concerns that there may be delays in shipping ingredients, such as SWE, into the US, which increases the cost to the manufacturers. For companies that purchase the product as ingredients in end-use products, there is the potential for a cost increase from suppliers, as well as having to secure proper transportation for products.

The potential economic impact on manufactures, per product, for rebranding, relabeling, and changes to the supply chain and logistics as a result of the Guidance is presented in Table 4.

Table 4. Annualized costs (5 years, 5% discount rate) of rebranding, relabeling, and changes to the supply chain and logistics.

Cost Estimate per Registered Product	Number of Registered Products			
	100	250	500	750
	Annualized costs over 5 years (thousand US$)			
Low Estimate ($5,000 for rebranding, $5,000 for relabeling, and $6,000 for supply chain and logistics)	$279	$698	$1,396	$2,093
High Estimate ($80,000 for rebranding, $25,000 for relabeling, and $95,000 for supply chain and logistics)	$3,489	$8,722	$17,445	$26,167

Additional Considerations

Due to the substantial costs associated with registering products as pesticides, manufacturers are concerned that they would be forced to exit the PBS market, which would not only impact the manufacturer but also customers who use their products (such as humic or fulvic acid) in end-use products and growers.

The economic burden extends beyond the manufacturers of PBS to the companies using the products to develop proprietary bulk prescription fertilizer blends for growers across the US. Many of the companies either market their own PBS products or utilize products manufactured by other companies to provide a custom product to growers. If ingredients, such as SWE, were registered as pesticides, companies marketing custom blends would face regulatory and marketing challenges. Both the companies that market the products, as well as the end-user (grower), would be negatively impacted by the change in the regulatory status of PBS.

While the annualized costs focus on the initial five years, there is the potential for future costs related to adding new uses or other changes to the label. Depending on the requested change, EPA and states may require additional data development related to the new use. Additional costs could be as high as the initial data development and registration costs; however, these costs were not included in the analysis due to the added layer of complexity and uncertainty.

Unlike pesticides, a centralized database of PBS marketed and purchased in the US does not exist, except for PBS certified as organic by OMRI. Additionally, most state fertilizer registries only include the option to search by product name, not by constituent substances/materials. It is difficult to estimate the true economic impact without a clear picture of the products currently being used by growers by crop and state. This analysis provides a range of estimated costs are based on best available data and input from manufacturers. While it is unlikely that the economic impact would be lower than estimated due to the assumptions used in the analysis, it is possible that the economic impact may be substantially greater depending on the actual number of products currently sold by manufacturers and applied by growers.

Table 5. Summary of Annualized Costs to Manufacturers (5 years at 5% Discount Rate)

Cost Categories	Increase in Annualized Costs to Manufacturers (thousand $US, Annual Costs for 5 years)	
	Low Estimate[a]	High Estimate
Data Development	$903	$65,417
Federal Registration	$767	$5,893
State Registration	$2,058	$2,032
OMRI	$60	$413
Production Costs: Rebranding, Relabeling, and Changes to Supply Chains and Logistics	$698	$26,167
Annualized Total Costs[b]	$4,485	$99,921
Annualized Total Costs including reduced manufacturers' revenue during registration[c]	$91,708	$449,813

[a] For data development and federal registration the low estimate is based on 250 products and the lowest cost option and the high estimate is based on 750 products and the highest cost option. For state registration, OMRI, and Production Costs, the low estimates are based on the lowest cost option and the high estimates are based on the highest cost option.

[b] The *annualized total costs* do not include the potential lost revenue due to limited marketing opportunities during the registration process, data development costs at the state level, costs related to companies exiting the PBS market, and costs to growers who are currently using the products as fertilizers.

[c] The *annualized total costs including reduced manufacturers' revenue during registration* includes the potential revenue that would be lost in California from reduced sales during the registration process based on a low estimate (50 companies at $5 million per company lost revenue in the first two years) and a high estimate (100 companies at $10 million per company each in the first two years).

Market Access for Biostimulant Products

Given the above description of the economic implications of the Guidance, it is reasonable to state that many of the PBS products that are in development may never make it to market if the Guidance is implemented as written. Companies will have to make decisions related to research and development, product testing, registration costs, marketing, and other related concerns if a more complicated and costly regulatory structure is required for certain PBS products going forward. Many companies will choose not to pursue the development of certain products and, not only will their product never reach the market, the end users will not have the opportunity to realize the benefits of the product.

Concluding Thoughts

We appreciate EPA's effort in the development of the Guidance, and consideration of these comments. As demonstrated in our comments, we see certain aspects of the Guidance as helpful and of assistance; however, the major concerns we have with Table 4 of the Guidance undermine the positive aspects of the Guidance.

As stated above, if the Guidance is implemented as written, there would likely be negative economic impacts on manufacturers, companies producing end-use products,

state regulatory agencies, and growers. For manufacturers, the annualized cost could reach or exceed $449 million, totaling over $2 billion for the five-year time period (Table 5). The estimated cost to manufacturers represents approximately half of the current global PBS market value, estimated at $4 billion.

The most significant potential costs are associated with data development both at the federal level and state level, particularly California, and the potential lost revenue to manufacturers during the registration process depending on the active ingredient of the product and the potential use sites. Table 5 summarizes the estimated annualized costs (5 years, 5% discount rate) of the Guidance based on a low estimate and a high estimate. The threat of lost revenue may lead companies to exit the PBS market or close their businesses. Without adequate capital, companies may not be able to withstand both the data development and registration costs, as well as a decrease in revenue.

Additionally, the estimate does not include the potential impact to growers due to delayed access to products during the registration process and/or lack of access to products no longer produced for marketing or use in a particular state. While reduced access to PBS would impact all growers currently using the products, it would have a greater impact on specialty crop growers, both conventional and organic.